Purpose: The Committee is charged with the initial review of grant applications for federal assistance in the program areas administered by the National Institute of Mental Health relating to psychiatry education and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda: From 10 a.m., June 12, through early afternoon, June 13, the meeting will be open for discussion of administrative announcements, program developments and review criteria in the light of new initiatives and priorities of the Institute.

Substantive program information may be obtained from the contact person listed above. The NIMH Information Officer who will furnish, upon request, summaries of the meeting and rosters of the committee members is Dr. Jacquelyn Hall, Acting Chief, Public Information Branch, Division of Scientific and Public Information, National Institute of Mental Health, Room 15C-17 Parklawn Building, 5600 Fishers Lane, Rockville, Md. 301-443-3473.

Dated: April 25, 1978.

CAROLYN T. EVANS,
Committee Management Officer Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 11701 Filed 5-1-78; 8:45 am]

[4110-88]

ADVISORY COMMITTEES

Meeting

In accordance with section 10(a)(2) the Federal Advisory Committee (5 U.S.C. Appendix I), announcement is made of the following National Advisory body scheduled to assemble during the month of June 1978:

EPIDEMIOLOGIC STUDIES REVIEW COMMITTEE

June 12-13, 9 a.m., University of Iowa, 500 Newton Road, Iowa City, Iowa. Open: June 12, 9 to 10 a.m. Closed: Otherwise. Contact: Lavinia Walsh, Room 10C-09, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3774.

Purpose. The Committee is charged with the initial review of grant applications for Federal assistance in the program areas administered by the National Institute of Mental Health relating to research and training activities in the field of epidemiology and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda. From 9 to 10 a.m., June 12, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of grant applications for Federal assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of section 552b(c)(6), title 5 U.S. Code and section 10(d) of Pub. L. 92-463 (5 U.S.C. Appendix I).

Substantive program information may be obtained from the contact person listed above. The NIMH Information Officer who will furnish upon request summaries of the meeting and rosters of the committee members is Dr. Jacquelyn Hall, Acting Chief, Public Information Branch, Division of Scientific and Public Information, NIMH, Room 15C-17, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4573.

Dated: April 26, 1978.

CAROLYN T. EVANS,
Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 78-11803 Filed 5-1-78; 8:45 am]

[4110-03]

Food and Drug Administration

ARTHRITIS ADVISORY COMMITTEE

Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 1770-776 (5 U.S.C. App. I)), the Food and Drug Administration announces the renewal of the Arthritis Advisory Committee by the Secretary, Department of Health, Education, and Welfare.

DATE: Authority for this committee will expire on April 5, 1980, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

Dated: April 24, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-11704 Filed 5-1-78; 8:45 am]

[4110-03]

TRANSFER OF ADMINISTRATIVE RESPONSIBILITY FOR DENTAL DEVICES PREVIOUSLY CONSIDERED OVER-THE-COUNTER DRUGS

Implementation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that the Food and Drug Administration (FDA) has transferred administrative responsibility for over-the-counter (OTC) dental devices from the Bureau of Drugs to the Bureau of Medical Devices (BMD). In addition, data and information developed by, and all submissions to, the Advisory Review Panel on OTC Dentifrices and Dental Care Agents on dental devices have been transferred to BMD. This action was taken to implement the medical device amendments of 1976, under which several products previously regarded as drugs now come within the definition of a medical device intended for human use.

FOR FURTHER INFORMATION CONTACT:

Joseph L. Hackett, Bureau of Medical Devices (HFK-403), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7443, or
William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of January 30, 1973 (38 FR 2781), the Commissioner of Food and Drugs requested the submission of data and information on all OTC dental care drug products. The data and information received in response to the notice have been reviewed by the FDA Advisory Review Panel on OTC Dentifrices and Dental Care Agents under the procedures in § 330.10 (21 CFR 330.10) for classifying OTC drugs as generally recognized as safe and effective and not misbranded and for establishing on OTC drug monograph for the products. On May 28, 1976, the medical device Amendments of 1976 (Pub. L. 94-295) were enacted and several products previously regarded as drugs and under review by the Panel were placed within the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)). The Commissioner has reviewed the articles previously regarded as drugs and has concluded that the following fall within the definition of a device: Denture cushions, dental adhesives, dental reliners and repair kits, denture cleansers, and plaque-disclosing kits.

In a notice published in the FEDERAL REGISTER of December 16, 1977 (42 FR 63472), the Commissioner issued a notice of implementation of the transitional provisions of the medical device amendments for articles previously considered new drugs or antibiotic drugs. The notice explained the transitional provisions of the amendments, listed generic types of medical devices previously regarded as drugs, explained which of these types are to be

subject to premarket approval requirements, indicated which Bureau in FDA regulates the products, and explained how manufacturers and importers can petition for changes in the regulatory classification of medical devices intended for human use.

This present notice announces that FDA has transferred the administrative responsibility for OTC dental care devices from the Bureau of Drugs to the Bureau of Medical Devices. In addition, the Advisory Review Panel on OTC dentifrices and dental care agents has recommended that the Commissioner transfer that portion of its report concerning articles now regarded as medical devices intended for human use, together with the data and information submitted in response to the January 30, 1973, notice to BMD. The Panel has prepared a summary representing its conclusions concerning the safety, effectiveness, and labeling, as OTC drugs, of denture cushions, dental adhesives, dental relineirs and repair kits, denture cleansers (all of which were reviewed by the Panel as "denture aids"), and plaque-disclosing kits. After it is approved by the Panel, the summary will be available as an appendix to the minutes of the appropriate Panel meeting. The summary has been prepared independently of FDA and does not necessarily represent the agency's position on these articles.

The data and information received by FDA in response to the January 30, 1973, notice which were classified by the Panel as applying to denture aids and dental plaque-disclosing agents have been transferred to BMD with the related data and information developed by the Panel. Persons will be notified by letter of the transfer to BMD of the data or information which they submitted on these products.

Dated: April 24, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-11703 Filed 5-1-78; 8:45 am]

[4110-03]

[Docket No. 75N-0139; DESI No. 9955]

CERTAIN ORAL PROTEOLYTIC ENZYMES

Denial of Hearing; Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs (1) denies a hearing and withdraws approval of two proteolytic enzyme products whose sponsor had requested a hearing but did not submit any data to support those requests and (2) withdraws approval of one proteolytic enzyme product whose sponsor did not request a hearing. The products have been used to control edema and inflammation associated with various disorders.

ADDRESS: Requests for an opinion of the applicability of this notice to a specific drug product should be directed to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, 5600 Fishers Lane, Rockville, Md. 20857.

EFFECTIVE DATE: May 12, 1978.

FOR FURTHER INFORMATION CONTACT:

Nathan J. Treinish, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 9955) published in the FEDERAL REGISTER of June 25, 1970 (35 FR 10393), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council (NAS-NRC), Drug Efficacy Study Group concerning oral proteolytic enzymes. The drugs were classified as possibly effective and lacking substantial evidence of effectiveness. The notice also stated that additional evidence was required to fully establish their effectiveness.

Data and clinical studies that were subsequently submitted by the sponsors were found not to support the effectiveness of the drugs, and in a notice of opportunity for hearing published in the FEDERAL REGISTER of July 24, 1975 (40 FR 30995) (DESI 9955) (Docket No. 75N-0139, formerly FDC-D-588), the Director of the Bureau of Drugs reclassified the drugs to lacking substantial evidence of effectiveness for all indications and proposed to withdraw approval of the new drug applications for the products. The holders of the new drug applications named below requested hearings and submitted supporting material concerning their drug products. The hearing requests are under review and will be the subject of a future FEDERAL REGISTER notice. Marketing of these drug products may continue pending a ruling on the hearing requests.

NDA 11-783; Orenzyme Enteric-coated Tablets containing 50,000 or 100,000 units of trypsin and 4,000 or 8,000 units of chymotrypsin; Merrell-National Laboratories, Division of Richardson-Merrell, Inc., 100 East Amity Rd., Cincinnati, Ohio 45215.

NDA 12-178; Chymoral enteric-coated Tablets containing trypsin and chymotrypsin equivalent to 50,000 or 100,000 units enzyme activity; Armour Pharmaceutical Co.

NDA 12-293; Papase Tablets containing enzymes extracted from carpapaya equivalent to 10,000 enzyme activity; Warner-Chilcot oratories, Division of Warner-L Pharmaceutical Co., 201 Tabor Rd., Morris Plains, N.J. 07950.

NDA 12-527; Ananase Enteric-coated Tablets containing bromelains equivalent to 50,000 or 100,000 units enzyme activity; William H. Rorer, Inc., 500 Virginia Dr., Fort Washington, Pa. 19034.

NDA 12-626; Avazyme Enteric-coated Tablets containing 20 mg chymotrypsin; Wampole Laboratories, Division of Denver Chemical Manufacturing Co., 35 Commerce Rd., Stamford, Conn. 06904.

NDA 12-724; that part of NDA 12-724 pertaining to Wilzyme Enteric-coated Tablets containing 50,000 units of proteolytic activity (approximately 3 to 1 ratio of trypsin activity to chymotrypsin activity); Wilson Laboratories, Division of Wilson Pharmaceutical and Chemical Corp., 2600 Bond St., Park Forest South, Chicago, Ill. 60466.

NDA 12-724; that part of NDA 12-724 pertaining to Chymolase Enteric-coated Tablets containing 50,000 units of protoeolytic activity (approximately 3 to 1 ratio of trypsin to chymotrypsin activity); distributed by the Warren-Teed Products Co., subsidiary of Rohm & Haas Co., 582 W. Goodale St., Columbus, Ohio 43215.

The current notice pertains or the following drugs which we included in the notice of July 2

I. THE DRUGS

NDA 9-955; Cytolav Capsules containing 7,000 Armour units chymotrypsin; formerly marketed by Armour Pharmaceutical Co., Division of Armour & Co., Greyhound Tower, Phoenix, Ariz 85077. Armour requested a hearing but did not submit any supporting data or argument.

NDA 11-908; Chymar Buccal Tablets containing 10,000 Armour units chymotrypsin; formerly marketed by Armour Pharmaceutical Co. Armour requested a hearing but did not submit any supporting data or arguments.

NDA 12-724; that part of NDA 12-724 pertaining to Haugase Enteric-coated Tablets, containing 50,000 units of proteolytic activity (approximately 3-to-1 ration of trypsin activity to chymotrypsin activity) distributed by Madland Laboratories, Inc., 125 W. Wisconsin Ave., Milwaukee, Wis 53203. Madland did not request a hearing.

No other person filed a written appearance of election as provided for by said notice. The failure to file such an appearance constitutes election by such persons not to avail themselves of the opportunity for a hearing.

All drug products that are identical, related, or similar to the drugs named above and are not the subject